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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,179	07/02/2003	Roland Kreutzer	14174-104USS/RIB001.3USD4	5239

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BOSTON, MA 02110

EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,179

Applicant(s)

KREUTZER ET AL.

Examiner

Tracy Vivlemore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>1</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The previous objections to the specification have been overcome by the amendments submitted April 22, 2005.

1. The amendment filed April 22, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment filed April 22, 2005 amends the claims to be directed to an isolated oligoribonucleotide consisting of two separate non-linked complementary strands that are 15-21 nucleotides in length. The amendment further requests amendments to the specification by replacement of the paragraph beginning at page 1, line 4 to recite the invention is directed to inhibition of gene expression using double stranded oligonucleotides. This amendment introduces new matter because it expands the scope of the disclosure to encompass both deoxy- and ribo-oligonucleotides while the original disclosure is directed to and claims only oligoribonucleotides. Additionally, the addition of the new paragraph entitled "Description of the Art" which recites that "Methods of inhibiting gene expression using double stranded oligonucleotides have been recently described" constitutes new matter because as described above, only oligoribonucleotides have been used in such methods.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

1. Claim 4 has been amended to recite a double stranded RNA (dsRNA) 15-21 nucleotides in length that is formed from two separate non-linked complementary strands. Claims 5-9 limit claim 4 by further defining the length of the dsRNA, the nature of the RNA transcript to which the dsRNA is complementary and the dsRNA and the degree of complementarity of the dsRNA.
2. The specification teaches on page 4 that the dsRNA has 10-1000 or preferably 15-49 base pairs. The specification discloses a single sequence 21 bases in length that is linked to its complementary sequence via a C18 linker that forms a disulfide bond. However, from the disclosure on page 19 it is clear that the only contemplated use of this 21mer is as a covalent complex with its complement (see lines 15-19), thus while the limitation that the dsRNA is 15-21 nucleotides in length finds support in the specification, the specification does not provide support for the claimed invention of dsRNA 15-21 bases in length that are two separate strands.

Double Patenting

The provisional obviousness-type double patenting rejection has been overcome by the filing of a terminal disclaimer.

Claim Rejections - 35 USC § 102

The rejection of claims 4, 5 and 7 as being anticipated by Kmiec has been overcome by the claim amendment of April 22, 2005. The oligonucleotides of Kmiec require at least 3 deoxynucleotides, while the instant claims are directed to oligoribonucleotides.

The rejection of claims 10-15 as being anticipated by Agrawal et al. is moot in view of the cancellation of these claims.

Priority

Based on the new matter issued raised in this action, the priority of the application is the instant filing date, July 2, 2003.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Fosnaugh et al. (US 2003/0143732).

3. Claim 4 is directed to an isolated double stranded RNA (dsRNA) consisting of two separate non-linked strands that are 15-21 nucleotides in length wherein one of the strands is complementary to less than a full-length RNA transcript of a mammalian gene that inhibits expression of the target gene. Claims 5-9 limit claim 4 by further defining the length of the dsRNA, the nature of the RNA transcript to which the dsRNA is complementary and the dsRNA and the degree of complementarity of the dsRNA.

4. Fosnaugh et al. disclose siRNAs that are 19-25 bases in length that may contains modifications to the phosphate backbone, nucleobase or sugar (see paragraphs 33 and 34). Fosnaugh et al. disclose siRNAs are capable of inhibiting gene expression in mammalian cells, particularly lung epithelial cells (see paragraph 251).

5. Thus, Fosnaugh et al. disclose and anticipate claims 4-9.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

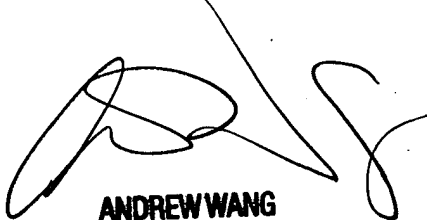
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also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
June 27, 2005



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